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10/809,157	03/25/2004	Keith E. Jasperson	151P9958US02	7387

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EXAMINER	
GILBERT, ANDREW M	
ART UNIT	**PAPER NUMBER**
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,157	JASPERSON ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 9/4/2007.

2. In the reply, the Applicant amended claims 1, 3 and added new claims 12 and 13.

3. Additionally, the Applicant amended the specification obviating the previous objection to the specification.

4. Thus, claims 1-13 are pending for examination.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-7, 9-13 rejected under 35 U.S.C. 102(e) as being anticipated by Hartlaub et al (2001/0037083). Hartlaub et al discloses a method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional, said implantable medical device being part of a system, comprising the steps of: manually programming said implanted device with a basal rate and a plurality

of interval rates over a specified period of time ([0010, 0030, 0032, 0037-0042]), each individual one of said interval rates corresponding to an individual one of a plurality of time slots during said specified period of time ([0010, 0030, 0032, 0037-0042]); said system determining a total dose over said specified period of time based on said basal rate and said interval rate ([0010, 0030, 0032, 0037-0042]); the system adjusting said basal rate so that said total dose does not exceed said maximum dose ([0010, 0030, 0032, 0037-0042]); and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates specified in said programming step ([0010, 0030, 0032, 0037-0042], see also the Response to Arguments below). In reference to claims 2-12, see ([0010, 0030, 0032, 0037-0042], and 304).

7. In reference to claim 13, Hartlaub et al additionally discloses manually adjusting at least one of said plurality of interval rates ([0010, 0030, 0032, 0037-0042], see also the Response to Arguments below); said system adjusting said basal rate in accordance with said plurality of interval rates as adjusted in said manually adjusting step ([0010, 0030, 0032, 0037-0042]); and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates ([0010, 0030, 0032, 0037-0042]).

8. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell (4731051). Fischell discloses a method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional (see Figs and

Summary), said implantable medical device being part of a system, comprising the steps of: manually programming said implanted device with a basal rate and a plurality of interval rates over a specified period of time (Summary), each individual one of said interval rates corresponding to an individual one of a plurality of time slots during said specified period of time (Summary, Figs); said system determining a total dose over said specified period of time based on said basal rate and said interval rate (Summary, Figs; col 5, lns 42-65; col 6, lns 65-col 7, lns 17; col 11, lns 33-62; col 20; col 30, lns 33-col 31, lns 63; col 32, lns 44-55); the system adjusting said basal rate so that said total dose does not exceed said maximum dose and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates specified in said programming step (Summary, Figs; col 5, lns 42-65; col 6, lns 65-col 7, lns 17; col 11, lns 33-62; col 20; col 30, lns 33-col 31, lns 63; col 32, lns 44-55). In reference to claims 2-12, see (Summary, Figs, especially Fig 21; col 5, lns 42-65; col 6, lns 65-col 7, lns 17; col 11, lns 33-62; col 20; col 30, lns 33-col 31, lns 63; col 32, lns 44-55).

In reference to claim 13, Fischell additionally discloses manually adjusting at least one of said plurality of interval rates; said system adjusting said basal rate in accordance with said plurality of interval rates as adjusted in said manually adjusting step; and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates (Summary, Figs; col 5, lns 42-65; col 6, lns 65-col 7, lns 17; col 11, lns 33-62; col 20; col 30, lns 33-col 31, lns 63; col 32, lns 44-55).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-10, 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boydman (5069668) in view of Fischell. Boydman discloses a method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional (Abstract; Summary), said implantable medical device being part of a system, comprising the steps of: manually programming said implanted device with a basal rate and a plurality of interval rates over a specified period of time (Abstract, Summary; col 8, lns 50-col 10, lns 33), each individual one of said interval rates corresponding to an individual one of a plurality of time slots during said specified period of time (Abstract, Summary; col 8, lns 50-col 10, lns 33); said system determining a total dose over said specified period of time based on said basal rate and said interval rate (Abstract, Summary; col 8, lns 50-col 10, lns 33); the system adjusting said basal rate so that said total dose does not exceed said maximum dose (Abstract, Summary; col 8, lns 50-col 10, lns 33); and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates specified in said programming step (Abstract, Summary; col 8, lns 50-col 10, lns 33). In reference to claims 2-12, see (Abstract, Summary; col 8, lns 50-col 10, lns 33 and col 13, lns 5-

25). In reference to claim 13, Boydman additionally discloses manually adjusting at least one of said plurality of interval rates; said system adjusting said basal rate in accordance with said plurality of interval rates as adjusted in said manually adjusting step; and delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates (Abstract, Summary; col 8, lns 50-col 10, lns 33).

11. Howevever, Boydman fails to teach that the infusion system is implantable. Fischell teaches that it is known to have an implantable infusion set for the purpose of providing appropriate control means to an implantable pump to deliver medication to a site in the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the infusion controls for an infusion pump as taught by Boydman with the infusion control for an implantable infusion pump as taught by Fischell for the purpose of appropriate control means to an implantable pump to deliver medication to a site in the body.

Double Patenting

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. Claims 1-11 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 25-35 of copending Application No. 10/278769. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The Examiner notes that the claims currently stand as withdrawn in copending Application No. 10/278769 and the Applicant has gone on the record stating that the claims 25-35 will be cancelled in the future. At the time the claims are cancelled the Examiner will withdraw the present rejection.

Response to Arguments

14. Applicant's arguments filed 9/4/2007 have been fully considered but they are not persuasive.

15. The Applicant argues that Hartlaub does not teach or suggest:

i. Adjusting the basal rate to not exceed a maximum dosage. (Remarks, pg 14, paragraph 1)

ii. Adjusting the basal rate at all, including not adjusting the basal rate in order to maintain the same dose in the even one of the interval rates is subsequently changed. (Remarks, pg 14, paragraph 5-pg 15, paragraph 1).

16. In response to the Applicant's argument (i) and (ii), the Examiner notes that Hartlaub discloses dose limits that determine a maximum and minimum amount of drug to be delivered per a unit of time (Abstract; [0010]). Hartlaub teaches dose infusion characteristics stored in member to limit the amount, frequency, or other characteristic(s) of dose of the drug to be given to the patient – and this can include a

program to limit the number of drug bolus deliveries over a 24-hour period ([0029-0030]). This is to prevent possible overdosing (as well as underdosing), such that the upper-limit, or maximum dosage, inputted by the physician is used as a fail safe to prevent overdosing ([0031-0032]). Further, drug infusion characteristics may include the maximum daily allowance dosage, 24 hour rolling average limits, nominal dosage rates – ie default rates, and minimum time intervals between bolus requests ([0037]). In a case (Fig 4, [0039]) where dosage administered should be decreased, the step 402 checks and determines whether the patient has requested a dose of medication in the specified time period – ie a bolus or interval dosage or via an increase in the basal rate. The time period is being disclosed as 1 or 1+ days or 1 or 1+ hours ([0039]). Based on the findings, the therapy program could *either* prompt the patient via notification to select a lower base rate to reduce drug usage *or* the program could activate the smallest programmed dose. This ensures that the base rate does not cause overmedication in conjunction with bolus, ie interval, doses ([0039]). Thus, Hartlaub explicitly teaches that the software therapy programming functions to adjust the basal rate to not exceed a maximum dose specified by the physician (also, [0040-0043]). Additionally, since the bolus, ie interval, rates may be changed by the patient or physician during a prescribed time period, the therapy program functions to monitor these changes in bolus rates and the dosage given to the patient to change the base rate to ensue the same total dose occurs and overdosing does not occur.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER